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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/798,941

03/10/2004

Ruud Philip Antoon Maria Segers

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05/01/2006

INTERVET INC.

PATENT DEPARTMENT

PO BOX 318

MILLSBORO, DE 19966-0318

EXAMINER

HINES, JANA A

ART UNIT

PAPER NUMBER

1645

DATE MAILED: 05/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/798,941

Applicant(s)

SEGERs ET AL.

Examiner

Ja-Na Hines

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 February 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on February 23, 2006 has been entered.

Amendment Entry

2. The amendment filed February 23, 2006 has been entered. The examiner acknowledges the amendment to the specification. Claims 1-19 have been cancelled. Claim 20 has been amended. Claim 20 is under consideration in this office action.

Priority

3. Applicant's claim for domestic priority under 35 U.S.C. 119(e) is acknowledged. However, the previous applications upon which priority is claimed fails to provide adequate support under 35 U.S.C. 112 for claim 20 of this application. 09/057,570 and 09/387,693 09/518,165 for which priority is claimed teach a nucleotide sequence wherein the nucleotide sequence comprises: the promoter region controlling of the *Actinobacillus pleuropneumoniae* repeat in toxin operon type IV (Apx IV) gene, from position 594 to 641 of SEQ ID NO:5 and a heterologous gene that is functionally linked

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to the promoter region. The specification, at pages 9-10 of the instant specification refers to the entire promoter region. Page 10, teach that bacterial promoters all share two consensus region, the so-called -10 and the -35 region, and that it can be advantageous to use only that part of the promoter region that comprises the DNA fragment between -35 and the ATG codon. However there is no teaching of a promoter region from position 594 to 641 of SEQ ID NO:5. Neither is there a teaching of nucleotide sequence comprising the promoter region controlling of the *Actinobacillus pleuropneumoniae* repeat in toxin operon type IV (Apx IV) gene, from position 594 to 641 of SEQ ID NO:5 and a heterologous gene that is functionally linked to the promoter region. It appears that the entire specification appears to fail to recite support for the newly recited nucleotide sequence. There was no conception of the instantly claimed nucleotide sequence. Thus, priority cannot be granted to 09/057,570 and 09/387,693 09/518,165 since what is now claimed, has not been previously recited in the other applications.

Withdrawal of Rejections

4. The following rejections have been withdrawn in view of applicants' amendments:
 - a) The rejection of claim 20 under 35 U.S.C. 112, second paragraph;
 - b) The rejection of claim 20 under 35 U.S.C. 101; and

Response to Arguments

5. Applicant's arguments with respect to claim 20 have been considered but are moot in view of the new ground(s) of rejection.

New grounds of Rejection
Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claim 20 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Neither the specification nor originally presented claims provides support for a nucleotide sequence wherein the nucleotide sequence comprises: the promoter region controlling of the *Actinobacillus pleuropneumoniae* repeat in toxin operon type IV (Apx IV) gene, from position 594 to 641 of SEQ ID NO:5 and a heterologous gene that is functionally linked to the promoter region.

Applicant did not point to support in the specification for a nucleotide sequence wherein the nucleotide sequence comprises: the promoter region controlling of the *Actinobacillus pleuropneumoniae* repeat in toxin operon type IV (Apx IV) gene, from position 594 to 641 of SEQ ID NO:5 and a heterologous gene that is functionally linked to the promoter region. Thus, there appears to be no teaching of an isolated nucleotide sequence as instantly claimed. There is disclosure of a promoter region from position

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594 to 641 of SEQ ID NO:5 and a heterologous gene. Applicant has pointed to page 9 of the instant specification and claims for support of the amendment which are drawn to the heterologous gene, however that passage refers to the entire promoter region. Page 10, para. 2 teach that bacterial promoters all share two consensus region, the so-called -10 and the -35 region, and that is : advantageous to use only that part of the promoter region that comprises the DNA fragment between -35 and the ATG codon. Thus, there is no teaching of a promoter region from position 594 to 641 of SEQ ID NO:5. It appears that the entire specification appears to fail to recite support for the newly recited nucleotide sequence wherein the nucleotide sequence comprises: the promoter region controlling of Apx IV gene, from position 594 to 641 of SEQ ID NO:5 and a heterologous gene that is functionally linked to the promoter region. Therefore, it appears that there is no support in the specification. Therefore, applicants must specifically point to page and line number support for the nucleotide sequence as recited by the new amendment. Therefore, the new claim incorporates new matter and is accordingly rejected.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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7. Claim 20 is rejected under 35 U.S.C. 102(b) as being anticipated by Segers et al., (EP 875,574). The claims are drawn to a nucleotide sequence wherein the nucleotide sequence comprises: the promoter region controlling of the *Actinobacillus pleuropneumoniae* repeat in toxin operon type IV (Apx IV) gene, from position 594 to 641 of SEQ ID NO:5 and a heterologous gene that is functionally linked to the promoter region.

Segers et al., teach live attenuated bacteria of the species *Actinobacillus pleuropneumoniae*. Segers et al., teach the unexpected advantage of brining the expression of a heterologous gene under the control of the ApxIV promoter (page 5, lines 33-34). The heterologous gene to be expressed can be functionally linked to the ApxIV promoter by replacing the coding sequence of the ApxIV gene with the coding region of the heterologous gene under the influence of the ApxIV promoter by making a fusion construct (page 5, lines 35-41). The promoter region is located in the DNA fragment between position 451-1132 of SEQ ID NO:5 (page 6, lines 5-6). It is clear that those parts of the DNA fragment that are not essential promoter elements need not be present in the fragment (page 6, lines 6-7). Thus shorter fragments of this DNA in which promoter activity is retained are equally suitable for expression (page 6, lines 6-10). Therefore a preferred embodiment comprises positions 451 to 1132 of SEQ ID NO:5 or a subfragment thereof still having promoter activity (page 6, lines 9-10). Segers et al., also teach that it may be advantageous to use only part of the promoter region that comprises the DNA fragment between -35 and the ATG codon (page 6, lines 12-14). Both positions 451 to 1132 of SEQ ID NO:5 and the DNA fragment between -35 and

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the ATG codon comprise positions 594 to 641 of SEQ ID NO:5, just as recited by the claim.

Thus, Segers et al., teach a nucleotide sequence wherein the nucleotide sequence comprises: the promoter region controlling of the *Actinobacillus pleuropneumoniae* repeat in toxin operon type IV (Apx IV) gene, from position 594 to 641 of SEQ ID NO:5 and a heterologous gene that is functionally linked to the promoter region, just as instantly claimed.

Double Patenting

8. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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9. Claim 20 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-6 of U.S. Patent No. 6,013,266.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the subject of US Patent 6,013,266 inherently comprises the instantly claimed nucleotide sequence.

The instant claims are drawn to a nucleotide sequence wherein the nucleotide sequence comprises: the promoter region controlling of the *Actinobacillus pleuropneumoniae* repeat in toxin operon type IV (Apx IV) gene, from position 594 to 641 of SEQ ID NO:5 and a heterologous gene that is functionally linked to the promoter region. However US Patent 6,013,266 are drawn to a live attenuated bacterium comprising a heterologous gene that is functionally linked to the promoter region of the ApxIV gene. Therefore the bacterium inherently comprises a nucleotide sequence wherein the nucleotide sequence comprising the promoter region of the Apx IV gene, having at least positions 594 to 641 of SEQ ID NO:5, and a heterologous gene that is functionally linked to the promoter region, just as instantly claimed. Therefore the US Patent comprises the instantly recited nucleotide sequence, just as the instant claims. Thus, a bacterium comprising the instantly recited nucleotide sequence is not patentably distinct from the other.

Conclusion

10. No claims allowed.

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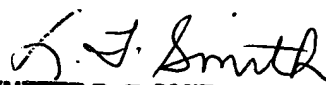
11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is 571-272-0859. The examiner can normally be reached on Monday-Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on 571-272-0864. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ja-Na Hines
April 24, 2006




LYNETTE R. F. SMITH
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600